

Sale of medicines by M/s. Wockhardt without approval

4605. SHRI VIJAY SINGH YADAV: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether it is a fact that M/s. Wockhardt are selling ACETEN without Price approval;
- (b) if so, what is the overcharged amount; and
- (c) what action has been taken by Government to recover this amount?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI SUKHDEV SINGH DHINDSA): (a) to (c) The formulation Aceten contains bulk drug Captopril, a scheduled bulk drug under the Drugs (Prices Control) Order, 1995. Ceiling prices (exclusive of Excise Duty) for 25 mg of Captopril were notified at Rs. 8.18 for 10's AL/ BL and at Rs. 8.48 for 10's AL/ST respectively vide S.O. 180(E) dated 09.03.1998. The notified MRP inclusive of Excise duty for the two packs works out to be Rs. 9.19 and Rs. 9.53 respectively.

M/s. Wockhardt Ltd., vide its letter dated 07.04.1999 informed the National Pharmaceutical Pricing Authority (NPPA) that they had discontinued manufacturing Aceten formulation from October 1998 and the price charged by them for the last batch produced was Rs. 9.45 for 10 tablets (25mg).

Presently, Aceten k being manufactured by M/s. Tridoss Labs Ltd., as per print on the Carton/Lable of the product. However, Aceten figures in the list of products appearing under the names of M/s. Wockhardt Ltd. as per the ORG-MARG (January, 2001) the Drug Today (October-December, 2000), where a maximum retail price inclusive of all taxes of Rs. 35.00 per pack of 10's strip is given.

Ceiling prices under DPCO, '95 are applicable to the Small Scale Units also. Accordingly, M/s. Tridoss Labs Ltd. was issued a show-cause notice under DPCO '95 by the NPPA on 03.07.2000 for recovery of the overcharge amount of Rs. 3,10,88,428/- As the reply to the show-cause notice given by the company was not satisfactory, NPPA wrote to the Collector, Moti Daman, under whose jurisdiction M/s. Tridoss Labs Ltd. is located, to recover the overcharged amount

as arrears of land revenue from the company. Meanwhile, M/fc. Tridoss Labs Ltd. have filed a Writ petition in the Bombay High Court on 16th April, 2001 against the show-cause notice of National Pharmaceutical Pricing Authority.

Sale of medicines without price approval by M/s. Hoechst

4606. SHRI VIJAY SINGH YADAV: Will the Minister, of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether it is a fact the M/s Hoechst are selling Avil, Proctosedyl and Sofradex without price approval;
- (b) if so, what are the details thereof;
- (c) what is the overcharged amounts, product-wise; and
- (d) what action has been taken by Government to recover the amount?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI SUKHDEV SINGH DHINDSA): (a) to (d) Avil, Proctosedyl and Sofradex are medicines based on scheduled bulk drugs under the Drugs (Price Control) Order, 1995 for which non-ceiling prices were approved to M/s. Roussel (I) Ltd. The company was renamed as M/ s. Hoechst Marion Roussel Ltd. (HMR). As per the price lists submitted by M/s. HMR from time to time, the company has been following the prices fixed by the Government. However, in the price list submitted by the company on 18.01.2000 (effective from 01.01.2000) the names of Avil Injections, Sofradex F Cream, Sofradex Cream and Protosedyl Ointment do not appear. It has come to the notice of the National Pharmaceutical Pricing Authority (NPPA) that these products have been manufactured by M/s. HUB Pharmaceuticals Ltd. Pune. That company has claimed that being an SSI, it is exempted from the non-ceiling prices under DPCO's 95. There are no ceiling prices for these packs. However, these products are shown as that of M/s. Hoechst Roussel in various medical journals like ORG-MARG (February, 2001) Drugs Today, the Indian Drug Review (IDR) and the MIMS. National Pharmaceutical Pricing Authority has served notices to M/s. HMR under DPCO '95